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DATE MAILED: 06/13/2005

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/519,224	03/06/2000	John C. Yundt-Pacheco	HEMA.69528	7948
27910 7:	590 06/13/2005		EXAM	INER
STINSON MORRISON HECKER LLP ATTN: PATENT GROUP			SUN, XIUQIN	
*	T STREET, SUITE 280	00	ART UNIT	PAPER NUMBER
	Y, MO 64106-2150		2863	

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)	Applicant(s)		
Office Action Summary		09/519,224	YUNDT-PACHEC	YUNDT-PACHECO, JOHN C.		
		Examiner	Art Unit			
		Xiuqin Sun	2863			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠	Responsive to communication(s) filed on 20	April 2005.				
2a)⊠	This action is FINAL . 2b) ☐ This action is non-final.					
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Dispositi	on of Claims					
5)⊠ 6)⊠ 7)□	/ 					
Applicati	on Papers					
9) 🗌	The specification is objected to by the Examir	ier.		·		
10)⊠ The drawing(s) filed on <u>06 March 2000</u> is/are: a)⊠ accepted or b)⊡ objected to by the Examiner.						
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notic	e of References Cited (PTO-892)		rview Summary (PTO-413)			
3) Inform	e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449 or PTO/SB/06 r No(s)/Mail Date	3) 5) 🔲 Noti	er No(s)/Mail Date ce of Informal Patent Application (PT0 er:	D-152)		

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DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed on 04/20/2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 10/683506 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 103

- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. Claims 56 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer et al. (U.S. Pat. No. 5646046) in view of Lin (U.S. Pat. No. 5532941) and further in view of Hopkins et al. (U.S. Pat. No. 6507765).

Fischer et al. teach a method for modifying data from a group of laboratory instruments (cols. 26-27, lines 56-11), comprising the steps of: obtaining data indicative of testing specimen outputs of a laboratory instrument (col. 6, lines 7-9; col. 7, lines 3-32; col. 26, lines 57-67 and col. 27, lines 1-11); and normalizing the data according to a reference (col. 7, lines 3-32; col. 19, lines 59-67; col. 20, lines 61-67; col. 21, lines 1-67; col. 22, lines 1-42; col. 26, lines 57-67 and col. 27, lines 1-12). The teaching of Fischer et al. includes: obtaining control specimen data and generating a normalization curve

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according to the control specimen data (col. 20, lines 61-67; col. 21, lines 1-67; and col. 22, lines 1-42). The teaching of Fischer et al. further includes: the normalization curve is generated for a single laboratory instrument (col. 5, 57-64; col. 21, lines 32-43; col. 26, lines 66-67), and can further be applied to each instrument in a group of laboratory instruments (col. 26, lines 60-67). The teaching of Fischer et al. further includes outputting the normalized data (col. 3, lines 58-59; and col. 21, lines 36-41).

Fischer et al. do not mention explicitly: obtaining data indicative of testing specimen outputs of a group of laboratory instruments; normalizing the data according to a control group, wherein the control group comprises data indicative of a comparison group of laboratory instruments; the outputting step includes displaying the normalized data on a network; modifying data from more than one group of laboratory instruments.

Lin teaches the steps and means of obtaining data indicative of outputs of a group of lab instruments; and normalizing the data according to a control group, wherein the control group comprises data indicative of a comparison group of laboratory instruments (Figs. 5 and 8A-8C; abstract; col. 2, lines 43-48, lines 53-56; col. 3, lines 6-11, lines 40-49, lines 60-63; col. 6, lines 5-28; col. 7, lines 57-67; col. 8, lines 1-67; col. 9, lines 1-34; col. 10, lines 21-67; col. 11, lines 1-12; col. 21, lines 66-67 and col. 22, lines 1-15); the outputting step includes sending the normalized data to the group of laboratory instruments (Fig. 5; col. 5, lines 26-29; col. 23, lines 16-27; and col. 25, lines 13-20).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the Lin group data collection, normalization technique

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and the computer system in the Fischer method in order to reduce the instrument-to-instrument variability in the data obtained from a group of lab instruments to allow comparative data analysis electronically without confusion or loss of confidence (Lin, abstract).

Hopkins et al. disclose a computerized control and information system for a manufacturing system, comprising a plurality of processing machines which generate signals indicative of the parameters of the processing machines' operation (col. 3, lines 11-17). Hopkins et al. teach the steps and means of providing a real-time summary and detailed analysis of received parameter signals, and displaying the summary data on a network including results of statistical analysis performed across said a plurality of processing machines (col. 8, lines 36-67; col. 9, lines 1-15 and lines 29-45).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the Hopkins et al. in the combination of Fischer and Lin in order to provide a network-based distributed computerized control and information system for a group of processing machines or laboratory instruments (Hopkins et al., col. 3, lines 11-17 and col. 9, lines 29-45).

Furthermore, in view of the teaching of Fischer et al. (col. 26, lines 56-67; col. 27, lines 1-11; col. 20, lines 20-26; col. 20, lines 61-67; col. 21, lines 1-67; and col. 22, lines 1-42), Lin (Figs. 5 and 8A-8C; abstract; col. 2, lines 43-48, lines 53-56; col. 3, lines 6-11, lines 40-49, lines 60-63; col. 6, lines 5-28; col. 7, lines 57-67; col. 8, lines 1-67; col. 9, lines 1-34; col. 10, lines 21-67; col. 11, lines 1-12; col. 21, lines 66-67 and col. 22, lines 1-15) and Hopkins (col. 3, lines 11-17; col. 8, lines 36-67; col. 9, lines 1-15 and lines 29-

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45), one having ordinary skill in the art would be able to apply the same technique to carry out the method for modifying instrument results to other groups of laboratory instruments. The mere application of a known method to more than one group of laboratory instruments by those skilled in the art would have been obvious.

Allowable Subject Matter

4. Claim 58 is allowed.

Reasons for Allowance

5. The following is an examiner's statement of reasons for allowance:

The primary reason for the allowance of claim 58 is the limitation that the groups of laboratory instruments comprise a laboratory information system coupled to individual laboratory instruments and in communication with the normalization server and wherein the groups of laboratory instruments send data indicative of outputs to the normalization system, and wherein the normalization system outputs normalized outputs to the groups of laboratory instruments. It is this limitation found in the claim, as it is claimed in the combination that has not been found, taught or suggested by the prior art of record, which makes this claim allowable over the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Response to Arguments

7. Applicant's arguments filed 4/20/2005 have been fully considered but they are not persuasive.

With respect to claims 56 and 57, the Applicant argued that "there is no suggestion in the cited prior art to make the suggested combination or modification".

This argument is not persuasive. The Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one

of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). The Examiner further recognizes that the test for obviousness is not whether the features of a second reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In this case, it is deemed that all three cited references are analogous art in the sense that they are either within the same field of endeavor or solving the same problem, directing to analysis and quality control of equipment/instrument to equipment/instrument variability. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine or modify the teachings of those references in order to make an improvement or an application of the known inventions.

Contact Information

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiuqin Sun whose telephone number is (571)272-2280. The examiner can normally be reached on 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Barlow can be reached on (571)272-2269. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 7, 2005

Xiuqin Sun Examiner Art Unit 2863